

Claims

1. A method for inducing an immune response, comprising:
topically administering to a subject an oil-in-water emulsion and an
5 immunostimulatory nucleic acid in an effective amount to induce an immune response.
2. The method of claim 1, wherein the immune response is an antigen specific
immune response.
- 10 3. The method of claim 1, further comprising administering an antigen.
4. The method of claim 1, wherein the immunostimulatory nucleic acid is a CpG
immunostimulatory nucleic acid.
- 15 5. The method of claim 1, wherein the subject has a cancer.
6. The method of claim 1, wherein the subject has an infectious disease.
7. The method of claim 1, wherein the subject is at risk of developing an
20 infectious disease.
8. The method of claim 6 or 7, wherein the infectious disease is a bacterial
infection or a fungal infection.
- 25 9. The method of claim 6 or 7, wherein the infectious disease is a viral infection.
10. The method of claim 9, wherein the viral infection is a human papilloma virus
infection, a herpes simplex virus infection or a herpes zoster virus infection.
- 30 11. The method of claim 1, wherein the oil-in-water emulsion and the
immunostimulatory nucleic acid is administered to the skin.

12. The method of claim 1, wherein the oil-in-water emulsion and the immunostimulatory nucleic acid is administered to a mucosal surface.

13. The method of claim 12, wherein the mucosal surface is an oral surface, a rectal surface, a nasal surface, a vaginal surface or an ocular surface.

14. The method of claim 1, further comprising administering an anti-viral agent.

15. The method of claim 14, wherein the anti-viral agent is selected from the group consisting of Acemannan; Acyclovir; Acyclovir Sodium; Adefovir; Alovudine; Alvircept Sudotox; Amantadine Hydrochloride; Aranotin; Arildone; Atevirdine Mesylate; Avridine; Cidofovir; Cipamfylline; Cytarabine Hydrochloride; Delavirdine Mesylate; Desciclovir; Didanosine; Disoxaril; Edoxudine; Enviradene; Enviroxime; Famciclovir; Famotone Hydrochloride; Fiacitabine; Fialuridine; Fosarilate; Foscarnet Sodium; Fosfonet Sodium; Ganciclovir; Ganciclovir Sodium; Idoxuridine; Kethoxal; Lamivudine; Lobucavir; Memotone Hydrochloride; Methisazone; Nevirapine; Penciclovir; Pirodavis; Ribavirin; Rimantadine Hydrochloride; Saquinavir Mesylate; Somantadine Hydrochloride; Sorivudine; Statolon; Stavudine; Tilorone Hydrochloride; Trifluridine; Valacyclovir Hydrochloride; Vidarabine; Vidarabine Phosphate; Vidarabine Sodium Phosphate; Viroxime; Zalcitabine; Zidovudine; and Zinviroxime.

16. The method of claim 1, wherein the immunostimulatory nucleic acid is a T-rich nucleic acid.

17. The method of claim 16, wherein the T-rich nucleic acid has a sequence selected from the group consisting of SEQ ID NOs: 52 - 57 and SEQ ID NOs: 62 - 94.

18. The method of claim 1, wherein the immunostimulatory nucleic acid is a poly-G nucleic acid.

19. The method of claim 18, wherein the poly-G nucleic acid has a sequence selected from the group consisting of SEQ ID NO: 46, SEQ ID NO: 47, SEQ ID NO: 58, SEQ ID NO: 61, and SEQ ID NOs: 95 -133.

20. The method of claim 1, wherein the immunostimulatory nucleic acid has a sequence selected from the group consisting of SEQ ID NOs: 1 - 146.

5 21. The method of claim 5, wherein the cancer is selected from the group consisting of melanoma , basal cell carcinoma, and cervical cancer.

22. The method of claim 1, wherein the immunostimulatory nucleic acid has a modified backbone.

10 23. The method of claim 22, wherein the modified backbone is a phosphate modified backbone.

15 24. The method of claim 23, wherein the phosphate modified backbone is a phosphorothioate modified backbone.

25. The method of claim 23, wherein the modified backbone is a peptide modified oligonucleotide backbone.

20 26. The method of claim 1, wherein the subject is an immunocompromised subject.

27. The method of claim 1, wherein the immunostimulatory nucleic acid has the nucleotide sequence of TCG TCG TTT CGT CGT TTT GTC GTT (SEQ ID NO:150).

25 28. The method of claim 1, wherein the immunostimulatory nucleic acid and oil-in-water emulsion is formulated for mucosal delivery.

30 29. The method of claim 1, wherein the immunostimulatory nucleic acid and oil-in-water emulsion is formulated for oral deliver, ocular delivery, nasal delivery, vaginal delivery or rectal delivery.

30. The method of claim 1, wherein the immunostimulatory nucleic acid and oil-in-water emulsion is formulated for skin delivery.

31. The method of claim 1, wherein the immunostimulatory nucleic acid has the
5 nucleotide sequence of TCG TCG TTT TGT CGT TTT GTC GTT (SEQ ID NO:147), TCG TCG TTT CGT CGT TTC GTC GTT (SEQ ID NO:148), TCG TCG TTT TTC GGT CGT TTT (SEQ ID NO:149), TCG TCG TTT TGT CGT TTT TTT CGA (SEQ ID NO:151), or TCG TCG TTT TTC GTG CGT TTT T (SEQ ID NO:152).

10 32. The method of claim 1, wherein the immunostimulatory nucleic acid has the nucleotide sequence of TCGTCGTTGTCGTTTTGTCGTT (SEQ ID NO:153).

33. The method of claim 1, wherein the subject has or is at risk of developing a condition selected from the group consisting of contact dermatitis, eczema, psoriasis, atopic
15 dermatitis, allergic contact dermatitis, and latex dermatitis.

34. The method of claim 1, wherein the immunostimulatory nucleic acid is a class A immunostimulatory nucleic acid, a class C immunostimulatory nucleic acid, a semi-soft immunostimulatory nucleic acid or a soft immunostimulatory nucleic acid.

20 35. The method of claim 1, wherein the subject has or is at risk of developing basal cell carcinoma and the immunostimulatory nucleic acid is TCG TCG TTT TGT CGT TTT GTC GTT (SEQ ID NO:147).

25 36. The method of claim 1, wherein the immune response is an innate immune response.

37. The method of claim 1, wherein the immune response is an adaptive immune response.

30 38. The method of claim 1, wherein the immune response is a local immune response.

39. The method of claim 1, wherein the subject is actively exposed to an antigen.

40. The method of claim 1, wherein the subject is passively exposed to an antigen.

5 41. A composition comprising
an immunostimulatory nucleic acid and an oil-in-water emulsion, formulated for
topical skin or mucosal delivery.

42. The composition of claim 41, further comprising administering an antigen.

10 43. The composition of claim 41, wherein the immunostimulatory nucleic acid is a
CpG immunostimulatory nucleic acid.

15 44. The composition of claim 41, wherein the oil-in-water emulsion and the
immunostimulatory nucleic acid is administered to a mucosal surface.

45. The composition of claim 44, wherein the mucosal surface is an oral surface, a
rectal surface, a nasal surface, a vaginal surface or an ocular surface.

20 46. The composition of claim 41, wherein the oil-in-water emulsion and the
immunostimulatory nucleic acid is administered to a skin surface.

47. The composition of claim 41, wherein the immunostimulatory nucleic acid is a
T-rich nucleic acid.

25 48. The composition of claim 47, wherein the T-rich nucleic acid has a sequence
selected from the group consisting of SEQ ID NOs: 52 - 57 and SEQ ID NOs: 62 - 94.

30 49. The composition of claim 41, wherein the immunostimulatory nucleic acid is a
poly-G nucleic acid.

50. The composition of claim 49, wherein the poly-G nucleic acid has a sequence selected from the group consisting of SEQ ID NO: 46, SEQ ID NO: 47, SEQ ID NO: 58, SEQ ID NO: 61 and SEQ ID NOs: 95 -133.

5 51. The composition of claim 41, wherein the immunostimulatory nucleic acid has a sequence selected from the group consisting of SEQ ID NOs: 1 - 146.

52. The composition of claim 41, wherein the immunostimulatory nucleic acid has a modified backbone.

10 53. The composition of claim 52, wherein the modified backbone is a phosphate modified backbone.

15 54. The composition of claim 53, wherein the phosphate modified backbone is a phosphorothioate modified backbone.

55. The composition of claim 53, wherein the modified backbone is a peptide modified oligonucleotide backbone.

20 56. The composition of claim 41, wherein the immunostimulatory nucleic acid has the nucleotide sequence of TCG TCG TTT TGT CGT TTT GTC GTT (SEQ ID NO:147), TCG TCG TTT CGT CGT TTC GTC GTT (SEQ ID NO:148), TCG TCG TTT TTC GGT CGT TTT (SEQ ID NO:149), TCG TCG TTT CGT CGT TTT GTC GTT (SEQ ID NO:150), TCG TCG TTT TGT CGT TTT TTT CGA (SEQ ID NO:151) or TCG TCG TTT TTC GTG
25 CGT TTT T (SEQ ID NO:152).

57. The composition of claim 41, wherein the immunostimulatory nucleic acid has the nucleotide sequence of TCGTCGTTGTCGTTTTGTCGTT (SEQ ID NO:153).

30 58. The composition of claim 41, wherein the immunostimulatory nucleic acid and oil-in-water emulsion is formulated for mucosal delivery.

59. The composition of claim 41, wherein the immunostimulatory nucleic acid and oil-in-water emulsion is formulated for oral delivery, ocular delivery, nasal delivery, vaginal delivery or rectal delivery.

5 60. The composition of claim 41, wherein the immunostimulatory nucleic acid and oil-in-water emulsion is formulated for skin delivery.

61. The composition of claim 41, wherein the immunostimulatory nucleic acid is a class A immunostimulatory nucleic acid, a class C immunostimulatory nucleic acid, a semi-
10 soft immunostimulatory nucleic acid or a soft immunostimulatory nucleic acid.